

**GOVERNMENT OF THE DISTRICT OF COLUMBIA
OFFICE OF THE INSPECTOR GENERAL**

DEPARTMENT OF HEALTH

**ENVIRONMENTAL
HEALTH ADMINISTRATION**

FINAL REPORT OF INSPECTION



**CHARLES C. MADDOX, ESQ.
INSPECTOR GENERAL**

Inspections and Evaluations Division
Mission Statement

The Inspections and Evaluations (I&E) Division of the Office of the Inspector General is dedicated to providing District of Columbia (D.C.) government decision makers with objective, thorough, and timely evaluations and recommendations that will assist them in achieving efficiency, effectiveness, and economy in operations and programs. I&E goals are to help ensure compliance with applicable laws, regulations, and policies, to identify accountability, recognize excellence, and promote continuous improvement in the delivery of services to D.C. residents and others who have a vested interest in the success of the city.

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General



August 1, 2003

Mr. James A. Buford
Director
Department of Health
825 North Capitol Street, N.E., Suite 4400
Washington, DC 20002

Dear Mr. Buford:

Enclosed is our final *Report of Inspection of the Environmental Health Administration*. Your agency's comments on the 9 findings and 11 recommendations by the inspection team are included in the Report.

In accordance with Mayor's Order 2000-105, District agencies are responsible for taking action on all agreed-upon recommendations in this final Report. The Office of the Inspector General (OIG) has established a process to track agency compliance and to facilitate our follow-up inspection activities. Enclosed are *Compliance Forms* on which to record and report to this Office any actions you have taken concerning each outstanding recommendation. These forms will assist you in tracking the completion of actions taken by your staff, and will assist this Office in its inspection follow-up activities. We track agency compliance with all agreed-upon recommendations made in our reports of inspection, and we request that you and your administrators establish response dates on the forms and advise us of those dates so we can enter them on our copies of the *Compliance Forms*.

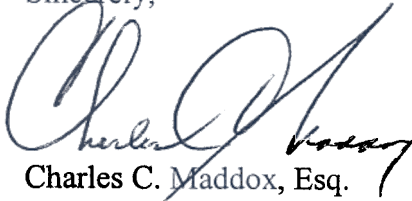
In some instances, things beyond your control, such as budget decisions, impact on trying to set specific deadlines. In those instances we request that you assign *target dates* based on whatever knowledge and experience you have about a particular issue. Please ensure that the *Compliance Forms* are returned to the OIG by the response date, and that reports of "Agency Action Taken" reflect actual completion, in whole or in part, of a recommended action rather than "planned" action. We will work closely with your designated point of contact throughout the compliance process.

We appreciate the cooperation shown by you and your employees during the inspection and we hope to continue in a cooperative relationship during the upcoming follow-up period.

Letter to James A. Buford
August 1, 2003
Page 2

If you have questions or require assistance in the course of complying with our recommendations, please contact me or Alvin Wright, Jr., Assistant Inspector General for Inspections and Evaluations at (202) 727-5052.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles C. Maddox". The signature is fluid and cursive, with a large initial "C" and a long, sweeping underline.

Charles C. Maddox, Esq.
Inspector General

CCM/AW/JCS/jcs

Enclosure

cc: See Distribution

DISTRIBUTION:

FULL REPORT

The Honorable Anthony A. Williams, Mayor, District of Columbia (1 copy)
Mr. John A. Koskinen, City Administrator, District of Columbia (1 copy)
Mr. Kelvin J. Robinson, Chief of Staff, Office of the Mayor (1 copy)
Mr. Tony Bullock, Director, Office of Communications (1 copy)
The Honorable Linda W. Cropp, Chairman, Council of the District of Columbia (1 copy)
The Honorable Vincent B. Orange, Sr., Chairman, Committee on Government Operations,
Council of the District of Columbia (1 copy)
Ms. Phyllis Jones, Secretary to the Council (13 copies)
Ms. Deborah K. Nichols, D.C. Auditor (1 copy)

EXECUTIVE SUMMARY¹

Mr. Robert J. Spagnoletti, Corporation Counsel, District of Columbia (1 copy)
Dr. Natwar M. Gandhi, Chief Financial Officer (4 copies)
Mr. Jeffrey C. Steinhoff, Managing Director, FMA, GAO (1 copy)
Ms. Jeanette M. Franzel, Director, FMA, GAO (1 copy)
The Honorable Eleanor Holmes Norton, D.C. Delegate, House of Representatives
Attention: Rosalind Parker (1 copy)
The Honorable Tom Davis, Chairman, House Committee on Government Reform
Attention: Peter Sirh (1 copy)
Ms. Shalley Kim, Legislative Assistant, House Committee on Government Reform (1 copy)
The Honorable Rodney Frelinghuysen, Chairman, House Subcommittee on D.C. Appropriations
(1 copy)
Ms. Carol Murphy, Staff Assistant, House Subcommittee on D.C. Appropriations (1 copy)
The Honorable Chaka Fattah, House Subcommittee on D. C. Appropriations
Attention: Tom Forhan (1 copy)
The Honorable George Voinovich, Chairman, Senate Subcommittee on Oversight of
Government Management, the Federal Workforce, and the District of Columbia (1 copy)
Ms. Theresa Prych, Professional Staff Member, Senate Subcommittee on Oversight of
Government Management, the Federal Workforce, and the District of Columbia (1 copy)
The Honorable Richard Durbin, Senate Subcommittee on Oversight of Government
Management, the Federal Workforce, and the District of Columbia (1 copy)
Ms. Marianne Upton, Staff Director, Senate Subcommittee on Oversight of Government
Management, the Federal Workforce, and the District of Columbia (1 copy)
The Honorable Mike DeWine, Chairman, Senate Subcommittee on D.C. Appropriations (1 copy)
Mr. Stan Skocki, Legislative Assistant, Senate Subcommittee on D.C. Appropriations (1 copy)
The Honorable Mary Landrieu, Senate Subcommittee on D.C. Appropriations (1 copy)
Ms. Kate Eltrich, Staff Director, Senate Subcommittee on D.C. Appropriations (1 copy)

¹ If you desire the full version of this report, you can read it online and download it from our website at www.dcig.org. You can also contact Relita Morgan at (202) 727-2540 for assistance in receiving a printed copy of the full report.

Letter to James A. Buford

August 1, 2003

Page 4

Mr. Charles Kieffer, Clerk, Senate Subcommittee on D.C. Appropriations (1 copy)

The Honorable Susan M. Collins, Chairman, Committee on Governmental Affairs

Attention: Johanna Hardy (1 copy)

The Honorable Joseph Lieberman, Committee on Governmental Affairs

Attention: Patrick J. Hart (1 copy)

TABLE OF CONTENTS

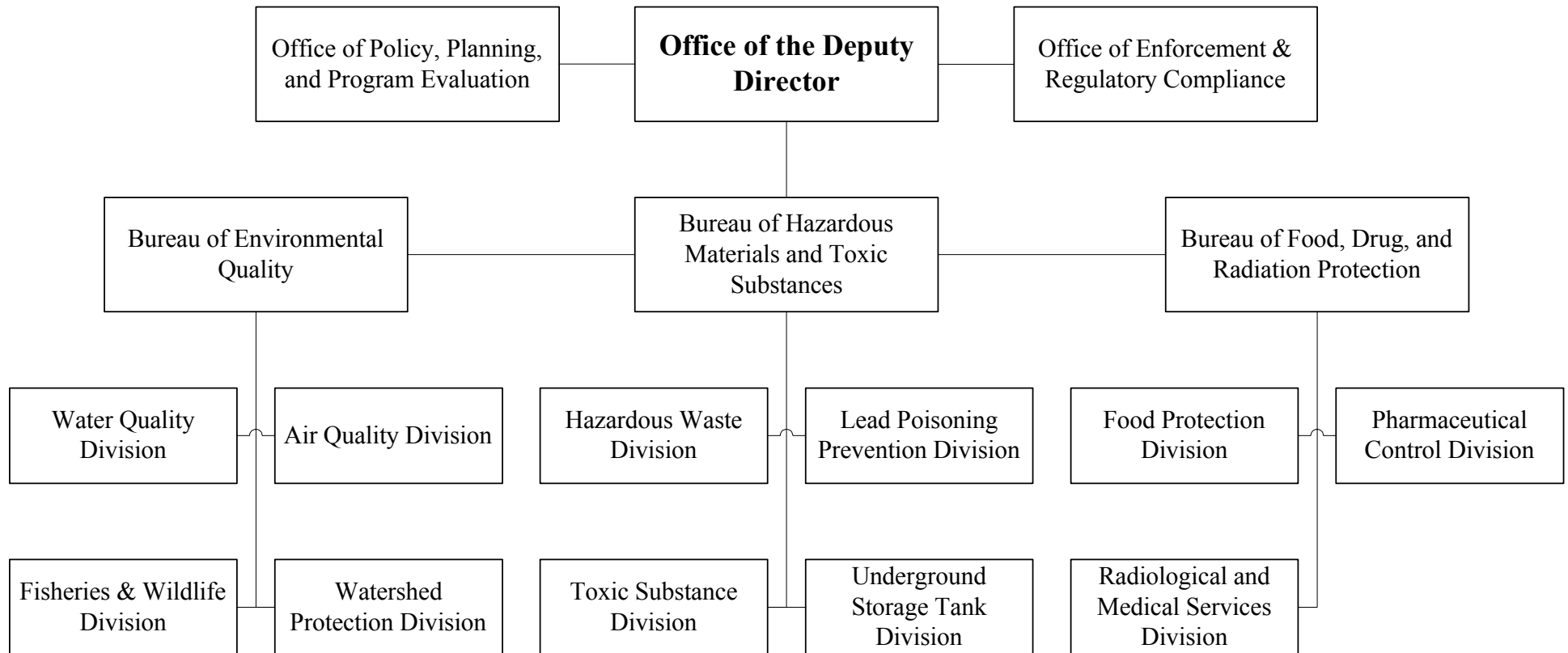
EXECUTIVE SUMMARY	2
INTRODUCTION.....	9
Background and Perspective	9
Scope and Methodology	9
Compliance and Follow-up	10
BUREAU OF FOOD, DRUG, AND RADIATION PROTECTION	13
Inspectors Do Not Have Enough Vehicles to Conduct Inspections.	13
Radiation Protection Division	14
X-Ray Machines Not Inspected and Not in Compliance With District Law.	14
Food Protection Division	15
Division Lacks Updated Listing of Food Establishments	16
FPD Employees Not Allowed to Meet Professional Training Requirements.	16
Pharmaceutical Control Division	17
Employees Shortage Delays Inspections and Other Duties.....	18
BUREAU OF HAZARDOUS MATERIALS AND TOXIC SUBSTANCES	21
Delays in Drawing Down Grant Funds Make Some Grants Unavailable.	21
Hazardous Waste Division	22
Insufficient Staffing Prevents Timely Annual Inspections.....	22
Inspectors Do Not Have Enough Vehicles to Conduct Inspections.	23
Underground Storage Tank Division	23
UST Division Surpassed the Mayor’s Scorecard Goal for Fiscal Year 2001.	24

ACRONYMS

BFDRP	Bureau of Food, Drug, and Radiation Protection
BHMTS	Bureau of Hazardous Materials and Toxic Substances
DOH	Department of Health
EHA	Environmental Health Agency
FPD	Food Protection Division
HWD	Hazardous Waste Division
RPD	Radiation Protection Division
SOAR	System of Accounting Records
USTD	Underground Storage Tank Division



Environmental Health Administration



EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

Background

The Inspector General (IG) directed the inspection of the Department of Health (DOH) in August 2001. Because DOH is such a large agency, major components were individually inspected between August 2001 and December 2002 and a separate report for each component was subsequently issued. This report evaluates two of three Bureaus comprising the Environmental Health Administration (EHA); the Bureau of Food, Drug, and Radiation Protection (BFDRP), and the Bureau of Hazardous Materials and Toxic Substances (BHMTS). Resource limitations precluded an inspection of the Bureau of Environmental Quality. OIG inspections comply with standards established by the President's Council on Integrity and Efficiency, and pay particular attention to the quality of internal control.¹

Perspective

EHA's mission is to prevent and control environmentally-related diseases, and to protect and preserve the ecological system and physical environment of the District. EHA provides services for the prevention and control of air pollution, abatement of asbestos, and the leakage of underground storage tanks. EHA strives to prevent environmentally-related disease and premature deaths that may be caused by exposure to hazardous materials and toxic substances. The Administration also performs inspections to ensure that food, drug, and medical device products are safe for public use.

Scope and Methodology

The inspection focused on the management, accountability, and operations of key areas, including the quality of operations, programs and projects, contracts and purchases, grants, and personnel management issues. The inspection team (team) conducted 19 interviews, toured 6 facilities, directly observed work processes, and reviewed pertinent files and documents. Management Alert Reports were provided to the Director of DOH (D/DOH) on the issues of DOH's noncompliance with District of Columbia (District) law for x-ray machine inspections and insufficient staffing for DOH's inspections of pharmaceutical sites. This report contains 9 findings and 11 recommendations, all of which were reviewed and commented on by DOH management prior to publication. EHA management and employees were cooperative and responsive throughout the inspection.

Compliance and Follow-Up

The inspection process includes follow-up with inspected agencies on findings and recommendations. The Inspections and Evaluations (I&E) Compliance Officer will coordinate with DOH on verifying compliance with recommendations in this report over an established time period.

¹ "Internal control" is synonymous with "management control" and is defined by the General Accounting Office as comprising "the plans, methods, and procedures used to meet missions, goals, and objectives and, in doing so, supports performance-based management. Internal control also serves as the first line of defense in safeguarding assets and preventing and detecting errors and fraud." STANDARDS FOR INTERNAL CONTROL IN THE FEDERAL GOVERNMENT, Introduction at 4 (Nov. 1999).

EXECUTIVE SUMMARY

FINDINGS AND RECOMMENDATIONS

Bureau of Food, Drug, and Radiation Protection

Inspectors do not have enough vehicles to conduct inspections. BFDRP inspectors stated that there is only one official vehicle for employees to conduct inspections. BFDRP management stated that grant funds have been allocated to purchase new vehicles; however, due to delays in drawing down grant funds, additional vehicles have not been purchased. Management stated that, in total, three vehicles are needed. The IG sent a Management Alert Report (MAR 02-I-005, Appendix 2) to D/DOH citing this issue and requesting notification of corrective actions taken. DOH's response stated that although the bureau has only two cars, 90 percent of the employees polled indicated the desire to use their own vehicles (Appendix 3). The BFDRP has identified funding for the purchase of 5 new automobiles in Fiscal Year (FY) 2003. Even with this vehicle shortage, BFDRP managers stated that BFDRP has never failed to meet its program measures. **Recommendation:** That D/DOH and the Chief of BFDRP take immediate action to ensure that BFDRP employees have the vehicles required to eliminate its inspection backlog and to conduct all inspections in a timely and effective manner in accordance with federal and District laws. (Page 13.)

DOH's Response to IG's Recommendation, as Received:

The BFDRP does not agree that there is a need to purchase additional vehicles for its inspectors. As stated in the DOH response to your MAR 02-I-005 report, dated April 26, 2002, 90 percent of staff polled would prefer and continue to use their personal vehicles. Currently there is funding available to cover mileage reimbursement for persons using their personal vehicles. Additionally, as indicated above performance indicators demonstrate that the lack of government vehicles has not hampered inspections.

Radiation Protection Division

The Radiation Protection Division (RPD) is not inspecting x-ray machines in compliance with District law and its own inspection policy. The team found that some x-ray machines being used in the District had not been inspected in as many as 10 years, in violation of both District law and DOH policy. In addition, the devices used to inspect x-ray machines were not properly calibrated. The IG sent a Management Alert Report (MAR 01-I-001, Appendix 4) to D/DOH citing these problems and requesting notification of corrective actions taken. DOH responded that it was taking immediate steps to hire qualified employees to inspect all x-ray machines in the District and was working with appropriate agencies to update all applicable regulations (Appendix 5). **Recommendations:** That D/DOH act quickly to hire qualified personnel to inspect x-ray machines on a regular basis according to District law and ensure that devices used to inspect x-ray machines are properly calibrated. (Page 14.)

a. DOH's Response to IG's Recommendation, as Received:

As of FY'02, all radiological equipment has been calibrated by Radcal Corporation and new equipment has been purchased. All scheduled inspections are on target with RPD's goal of 750 inspections per year. Additionally, during FY' 02, RPD exceeded its goal of inspecting radiation devices.

EXECUTIVE SUMMARY

b. DOH's Response to IG's Recommendation, as Received:

A Program Manager for the RPD has been hired as of January 2002. The Bureau will hire additional staff when funding and position authority becomes available. It is the RPD's policy to inspect all x-ray machines every two years. It should be noted that during FY' 02 the RPD completed 110% of its program measures with respect to inspections of x-ray machines.

c. DOH's Response to IG's Recommendation, as Received:

The Bureau is in the process of updating its standard operating procedures to reflect its policy of x-ray machine inspections, which will be completed by June 30, 2003. Additionally, the RPD is in the process of adopting the federal suggested state regulations on radiation. It is anticipated that the updated SOPs will be sent forward to Council for approval by the end of FY'04.

Food Protection Division

The Food Protection Division (FPD) does not have an automated database system or access to updated listings of the District's food and non-food establishments. The team found that current automated listings of District food and non-food establishments are housed at the licensing division of the Department of Consumer and Regulatory Affairs (DCRA). FPD maintains its lists on routing cards that are filed manually. Employees stated that DCRA does not provide FPD with the automated lists, and that manually maintaining card files is time consuming. Employees additionally stated that FPD has a database system, but that the food and non-food establishments listings have not been incorporated into the database.

Recommendation: That D/DOH and the Chief of BFDRP obtain current listings from DCRA and ensure that a database is developed for filing and updating the listing of food and non-food establishments. (Page 16.)

a. DOH's Response to IG's Recommendation, as Received:

The Bureau has collaborated with senior management of DCRA in an effort to coordinate information exchange between DOH and DCRA. Over the last three years the Bureau has been developing a proprietary computer program entitled "Permits Plus". This program enables the Bureau to generate computer listings of all restaurants to be inspected. This system meets the needs of the FPD, thus eliminating the need for access to DCRA's database as a means of information retrieval.

b. DOH's Response to IG's Recommendation, as Received:

The Bureau has developed a computer database, Permits Plus, that is fully operational and currently being utilized by BFDRP inspectors.

EXECUTIVE SUMMARY

FPD employees are not receiving the training needed to meet professional training requirements. Employees stated that management does not allow them to attend training or continuing-education classes that are recommended by federal and local government jurisdictions. They stated that training classes on food, pharmacy, and radiation safety are needed in order to maintain the skills, licenses, and certifications required to conduct inspections. **Recommendation:** That D/DOH and the Chief of FPD allow FPD inspectors to attend training classes to obtain and enhance skills, licenses, and certification. (Page 16.)

DOH's Response to IG's Recommendation, as Received:

The Bureau has always and will continue to encourage employees to engage in continuing-education training. Our latest effort was to have all employees become certified food handlers. Within budgetary constraints, all costs associated with such certifications will continue to be incurred by the Bureau.

Pharmaceutical Control Division

The Pharmaceutical Control Division (PCD) has only four licensed pharmacists to inspect 266 pharmaceutical sites. The team found that although the annual goal of pharmacy inspections is being met, inspections of other facilities that handle pharmaceuticals have not been conducted. The staff pharmacist stated that these inspections are not being done because of competing duties such as investigations for medical fraud, inspections of hospitals without pharmacies, research facilities, local wholesalers/distributors, long-term care and community facilities, animal and ambulatory clinics, dialysis centers that dispense controlled substances, and preparation of court consent decrees and responses to complaints. The OIG identified this issue in two Management Alert Reports, MAR 02-I-001 (Appendix 4), and MAR 02-I-005 (Appendix 2). DOH's response to MAR 02-I-001 states that "DOH's Health Regulation Administration has committed to provide for a pharmacist to conduct work as it relates to hospitals, long term care facilities, day care facilities, renal dialysis centers, animal clinics and ambulatory care clinics" (Appendix 5). DOH's response to MAR 02-I-005 states that all drug-handling facilities in the last fiscal year were inspected as reported by the Program Manager (Appendix 3). **Recommendation:** That the D/DOH and the Chief of BFDRP ensure that additional pharmaceutical employees are hired to conduct all required inspections and other tasks assigned to the Division. (Page 18.)

DOH's Response to IG's Recommendation, as Received:

The Bureau currently has sufficient staff to carry out all of its assigned responsibilities. To date, PCD is on target with scheduled inspections of all drug handling facilities.

Bureau of Hazardous Materials and Toxic Substances

Systemic weaknesses were found in the way EHA transfers grant funds during the lifetime of the grant. The team found that the DOH Chief Financial Officer (CFO) is not drawing down grant funds in a timely manner. It takes approximately 8 months for funds to be transferred into the System of Accounting Records (SOAR) database. This delays hiring new employees and purchasing equipment needed for day-to-day operations. Also, the team found

EXECUTIVE SUMMARY

that there was no contact or liaison person to resolve procurement request questions or concerns with the database management system. **Recommendation:** That D/DOH ensure that grant funds are drawn down in a timely manner during the lifetime of the grant. (Page 21.)

DOH's Response to IG's Recommendation, as Received:

The BHMTS agrees that grant funds should be drawn down promptly and accurately. Once a grant award letter has been received from the grantor, the program submits the letter to the DOH CFO. Once the award letter is submitted to the DOH CFO, the program has little control over the timeliness of the actual grant loading. Additionally, once a certificate of service has been provided by the program to the DOH CFO, the program has little control over the timeliness of the actual completion of draw downs. In particular, the administrative office overseeing the BHMTS, the Office of the Senior Deputy Director for Environmental Health Science and Regulation, does have staff that work as a liaison with the CFO to improve the grant process. The DOH CFO should be able to provide a more thorough response to this recommendation.

The Hazardous Waste Division (HWD) has only 2 inspectors to conduct 124 annual inspections. The team found that HWD has only 2 inspectors who cannot timely conduct 124 annual inspections, as well as handle emergency inspections, customer complaints, and license renewals for District and federal facilities that generate hazardous waste. The team found that some federal facilities have not been inspected for license renewal in 10 years.

Recommendation: That D/DOH hire additional inspectors to ensure that all division responsibilities are fulfilled in a timely manner. (Page 22.)

DOH's Response to IG's Recommendation, as Received:

The HWD does agree that additional inspectors are required. However, the Division does not have additional grant funding to increase the number of inspectors, nor has the DOH CFO appropriated money for this purpose. The DOH CFO should be able to provide a more thorough response to this recommendation.

Inspectors do not have enough vehicles to conduct inspections. HWD inspectors stated that they need three official vehicles to conduct required inspections; however, there is only one official vehicle available. BHMTS management stated that funds are available to purchase new vehicles, but due to delays in drawing down grant funds, additional vehicles cannot be purchased. The IG alerted DOH to this issue in a Management Alert Report (MAR 02-I-005, Appendix 2) and DOH responded that it had identified funding for the purchase of five new automobiles for inspectors (Appendix 3). **Recommendation:** That D/DOH provide the funds needed to purchase additional vehicles for the HWD inspectors. (Page 23.)

DOH's Response to IG's Recommendation, as Received:

The HWD does agree that additional vehicles are required. However, the Division does not have additional grant funding to increase the number of vehicles, nor has the DOH CFO appropriated money for this purpose. The DOH CFO should be able to provide a more thorough response to this recommendation.

EXECUTIVE SUMMARY

The Underground Storage Tank Division (USTD) surpassed the Mayor's scorecard goal for FY 2001. The inspection team found that the UST division had conducted 225 inspections for FY 2001. The USTD received an award for outstanding achievement for excellence from the U.S. Environmental Protection Agency (EPA). **Recommendation:** None. (Page 24.)

INTRODUCTION

INTRODUCTION

Background and Perspective

The Inspector General (IG) directed the inspection of the Department of Health (DOH) in August 2001. Because DOH is such a large agency, major components were individually inspected between August 2001 and December 2002 and a separate report for each component was subsequently issued. This report evaluates two of three Bureaus comprising the Environmental Health Administration (EHA); the Bureau of Food, Drug, and Radiation Protection (BFDRP), and the Bureau of Hazardous Materials and Toxic Substances (BHMTS). Resource limitations precluded an inspection of the Bureau of Environmental Quality. Although day-to-day EHA functions were being performed adequately, the OIG inspection team (team) found significant deficiencies in all inspected areas. Some of these deficiencies, however, are beyond the control of division managers and need to be addressed by senior EHA and DOH management.

The mission of EHA is to prevent and control environmentally-related diseases and protect and preserve the ecological system and the physical environment of the District of Columbia (District).

EHA provides several of DOH's core services:

- ensures that all underground storage tank facilities are leak-free and all remediation areas are free of hazardous contaminants;
- provides lead-screening for children;
- ensures that food and non-food establishments are clean, and that proper food handling practices are in place;
- ensures that all medical supplies in pharmaceutical establishments are inspected and in compliance with District and federal standards; and
- ensures that all x-ray and mammography machines are inspected and in compliance with District and federal standards.

Scope and Methodology

The team held an entrance conference with Ivan C. A. Walks, M.D., then Director, Department of Health² and Chief Health Officer for the District. Walks stated that he welcomed the inspection and suggestions from the team to improve the Department's overall performance and delivery of services to District stakeholders.

The team conducted interviews, observed work processes where possible, reviewed pertinent files and documents, and toured facilities licensed and inspected by EHA.

² James A. Buford is currently the Director of the Department of Health.

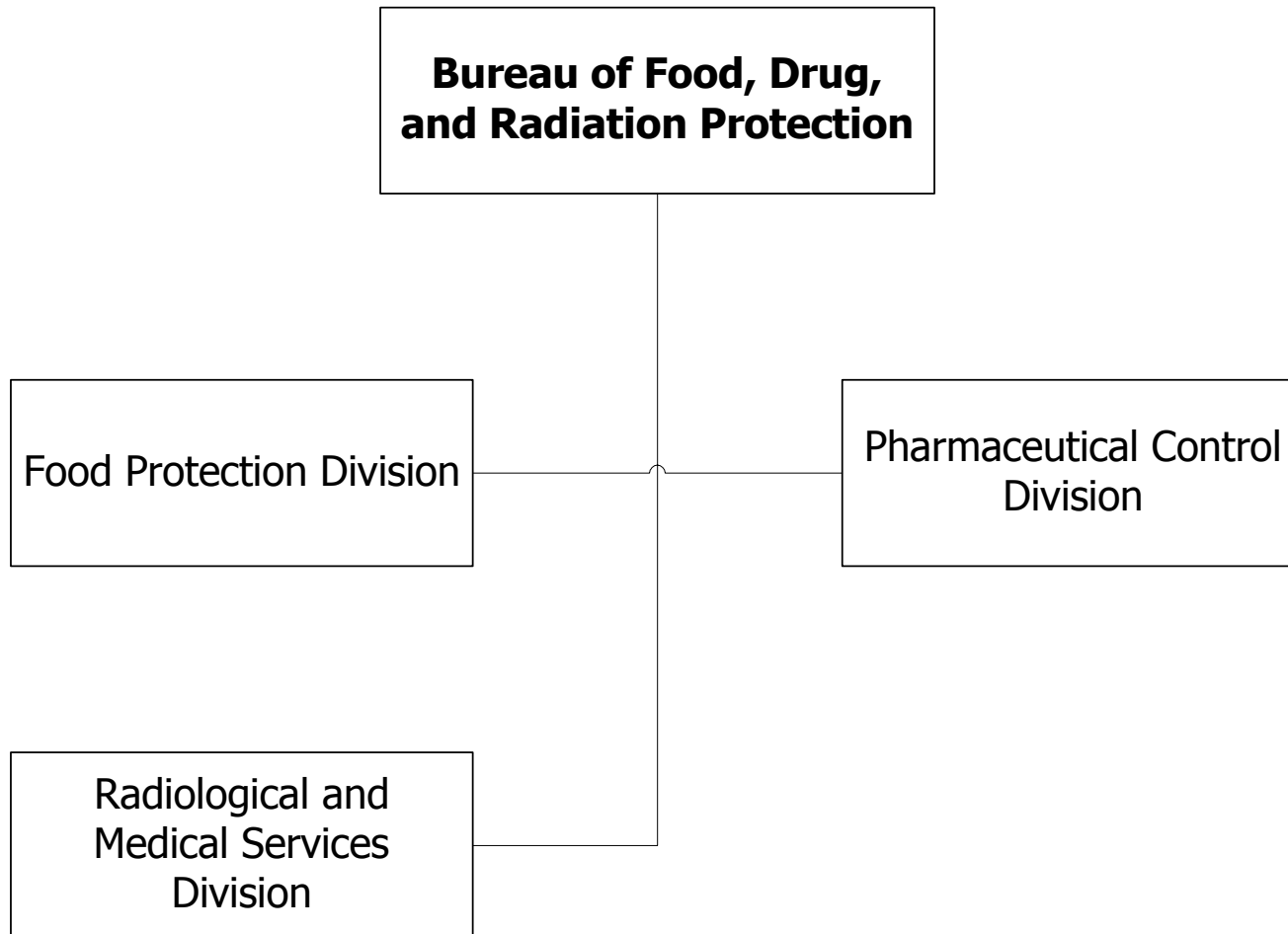
INTRODUCTION

Compliance and Follow-up

The inspection process includes follow-up with inspected agencies on findings and recommendations. The Inspections and Evaluations (I&E) Compliance Officer will coordinate with EHA on verifying compliance with the recommendations in this report over an established time period.



Environmental Health Administration



Findings and Recommendations:

BUREAU OF FOOD, DRUG, AND RADIATION PROTECTION

BUREAU OF FOOD, DRUG, AND RADIATION PROTECTION

The Bureau of Food, Drug, and Radiation Protection (BFDRP) was formerly part of the D.C. Department of Consumer and Regulatory Affairs (DCRA). In 1998, BFDRP was transferred to DOH under the Environmental Health Administration (EHA). The bureau is divided into three divisions: Radiation Protection Division, Food Protection Division, and Pharmaceutical Control Division.

1. BFDRP inspectors do not have enough vehicles needed to conduct daily inspections.

BFDRP inspectors stated that there is only one official vehicle for employees to conduct inspections. BFDRP management stated that grant funds have been allocated to purchase new vehicles; however, due to delays in drawing down the grant funds, additional vehicles have not been purchased. Management stated that three vehicles are needed in total. The IG sent a Management Alert Report (MAR 02-I-005, Appendix 2) to Director of DOH (D/DOH) citing this problem and requesting notification of corrective actions taken. DOH's response confirmed that the bureau has only two cars; however, DOH asserted that 90 percent of employees polled indicated a desire to use their own vehicles (Appendix 3). The BFDRP has identified funding for the purchase of 5 new automobiles in Fiscal Year (FY) 2003. BFDRP management states that despite the vehicle shortage, it has never failed to meet its program measures.

Recommendation:

That D/DOH and the Chief of BFDRP ensure that BFDRP employees have the vehicles necessary to conduct all inspections in a timely and effective manner in accordance with federal and District laws.

Agree _____ Disagree X

DOH's Response to IG's Recommendation, as Received:

The BFDRP does not agree that there is a need to purchase additional vehicles for its inspectors. As stated in the DOH response to your MAR 02-I-005 report, dated April 26, 2002, 90 percent of staff polled would prefer and continue to use their personal vehicles. Currently there is funding available to cover mileage reimbursement for persons using their personal vehicles. Additionally, as indicated above performance indicators demonstrate that the lack of government vehicles has not hampered inspections.

BUREAU OF FOOD, DRUG, AND RADIATION PROTECTION

Radiation Protection Division

The Radiation Protection Division (RPD) was established in 1980, and its mission is to minimize and/or eliminate over-exposure of persons to naturally occurring and artificial radiation in the District.

The Division is responsible for the biennial registration and inspection of 1,500 x-ray machines and 29 mammography machines located in the District.

2. The RPD is not inspecting x-ray machines in compliance with District law and its own inspection policy.

Title 20 DCMR § 2103.10 states that “[e]ach radiation device (x-ray machine) used in the District shall be re-tested at not longer than six (6) month intervals, or at intervals not to exceed three (3) years as is specified in the label required by this section.”³

The chief of RPD stated that his Division’s policy is to inspect all x-ray machines every 2 years. However, RPD’s standard operating procedures do not identify an inspection interval for x-ray machines. In addition, the team determined that some x-ray machines had not been inspected in as many as 10 years, and some devices used to inspect x-ray machines were not calibrated properly.

The IG sent a Management Alert Report (MAR 02-I-001, Appendix 4) to D/DOH citing these problems and asking to be notified of corrective actions taken. DOH responded that it had hired a highly qualified physicist and was working with appropriate agencies to update all applicable regulations (Appendix 5).

Recommendations:

- a. That D/DOH ensure the proper calibration of devices used to inspect x-ray machines.

Agree **X** Disagree

DOH’s Response to IG’s Recommendation, as Received:

As of FY’02, all radiological equipment has been calibrated by Radcal Corporation and new equipment has been purchased (see Attachments 1-4). All scheduled inspections are on target with RPD’s goal of 750 inspections per year. Additionally, during FY’ 02, RPD exceeded its goal of inspecting radiation devices.

³ This provision will be recodified at 22 DMCR § 6803.10.

BUREAU OF FOOD, DRUG, AND RADIATION PROTECTION

- b. That D/DOH act quickly to hire qualified contract or permanent employees to inspect all x-ray machines at regular intervals according to District law and DOH regulations.

Agree X Disagree

DOH's Response to IG's Recommendation, as Received:

A Program Manager for the RPD has been hired as of January 2002. The Bureau will hire additional staff when funding and position authority becomes available. It is the RPD's policy to inspect all x-ray machines every two years. It should be noted that during FY' 02 the RPD completed 110% of its program measures with respect to inspections of x-ray machines.

- c. That D/DOH ensure that 20 DCMR § 2103.10 and the standard operating procedures of the RPD are clarified and updated to reflect clear time limits for the inspection of all District x-ray machines.

Agree X Disagree

DOH's Response to IG's Recommendation, as Received:

The Bureau is in the process of updating its standard operating procedures to reflect its policy of x-ray machine inspections, which will be completed by June 30, 2003. Additionally, the RPD is in the process of adopting the federal suggested state regulations on radiation. It is anticipated that the updated SOPs will be sent forward to Council for approval by the end of FY'04.

Food Protection Division

The Food Protection Division (FPD) was established during the early 1940's, and its mission is to ensure that residents and visitors in the nation's capital consume safe and wholesome food. FPD's mission is carried out by administering a priority-based inspection program designed to address risk factors known to contribute to food-borne illness.

FPD is responsible for inspecting 4,700 food establishments in the District such as boarding homes, liquor stores, packaged food facilities, dairies, delicatessens, bakeries, candy manufacturers, grocery stores, retail markets, ice cream manufacturers, restaurants, wholesale markets, hotels, public schools, beauty and barber shops, food vending vehicles, and swimming pools.

Inspections are conducted quarterly, except for vending and mobile food vending sites which are conducted bi-annually. Inspections are unannounced and are normally conducted during a facility's regular business hours. Complaint inspections of situations that are not potentially hazardous are investigated within two working days. Complaints concerning situations that pose a danger to public health and safety – such as food-borne illness, lack of water, foods that are stored at incorrect temperatures, and sewage backups – are inspected immediately.

BUREAU OF FOOD, DRUG, AND RADIATION PROTECTION

3. **FPD lacks ready access to updated listings of District food establishments needed to perform inspections.**

DCRA generates an automated listing of all licensed restaurants in the District. A list is generated when restaurant owners register for a certificate of occupancy and operation. FPD employees stated that they do not have access to DCRA's automated list and that DCRA does not routinely provide it to them. FPD maintains a list of food establishments on file cards. FPD employees stated that in order to maintain information on restaurant and other food establishments that have to be inspected, an inordinate amount of time is spent creating, retrieving, and manually filing records. This outdated card system decreases inspectors' operational effectiveness, does not provide a way to back-up information, and is time-consuming. FPD employees also stated that although FPD has a database system, all lists have not been incorporated into the database.

Recommendations:

- a. That D/DOH and the Chief of BFDRP coordinate with DCRA to ensure that a computer listing of all restaurants to be inspected is generated and maintained at FPD.

Agree _____ Disagree X

DOH's Response to IG's Recommendation, as Received:

The Bureau has collaborated with senior management of DCRA in an effort to coordinate information exchange between DOH and DCRA. Over the last three years the Bureau has been developing a proprietary computer program entitled "Permits Plus". This program enables the Bureau to generate computer listings of all restaurants to be inspected. This system meets the needs of the FPD, thus eliminating the need for access to DCRA's database as a means of information retrieval.

- b. That the Chief of BFDRP ensure that a computer database is developed that can retrieve the restaurant listings directly from DCRA's database.

Agree _____ Disagree X

DOH's Response to IG's Recommendation, as Received:

The Bureau has developed a computer database, Permits Plus, that is fully operational and currently being utilized by BFDRP inspectors.

4. **Many FPD employees say they have not received the training required to maintain the skills, licenses, and certifications necessary to conduct inspections.**

Employees stated that management does not allow them to attend training or continuing-education classes that are recommended by federal and local government jurisdictions. They stated that training classes on food, pharmacy, and radiation safety are needed in order to

BUREAU OF FOOD, DRUG, AND RADIATION PROTECTION

maintain the skills, licenses, and certifications required to conduct inspections. If they lack this training, FPD inspectors may not be sufficiently knowledgeable about current trends in their field, and may conduct less comprehensive inspections of District facilities.

The IG sent a Management Alert Report (MAR 02-I-005, Appendix 2) to D/DOH citing these problems and asking to be notified of corrective actions taken. DOH's response was that only one employee, the mammography health physicist, is required by contract with the Federal Government to receive specialized training (Appendix 3). This health physicist has received certification that will not require renewal until 2005. DOH stated that the Bureau encourages employees to take courses to increase their knowledge, and noted that one employee in the FPD has attended 25 classes since 1999. According to DOH, the Bureau has invested over 2,000 hours for training and classes for employees on an annual basis.

Recommendation:

That D/DOH and the Chief of FPD allow FPD inspectors to attend continuing-education training to obtain and enhance skills, licenses, and certification.

Agree X Disagree _____

DOH's Response to IG's Recommendation, as Received:

The Bureau has always and will continue to encourage employees to engage in continuing-education training. Our latest effort was to have all employees become certified food handlers. Within budgetary constraints, all costs associated with such certifications will continue to be incurred by the Bureau.

Pharmaceutical Control Division

The Pharmaceutical Control Division (PCD) was established in 1982 by DCRA. In 1998, PCD was transferred to DOH. The Division has four certified pharmacists, one of whom serves as a program manager. The PCD's mission is to promote and protect public health by designing and administering the District's regulatory program, which ensures that the pharmaceutical products and services that are available for public consumption and use are safe for their intended purposes.

PCD is responsible for inspecting and monitoring 226 pharmaceutical sites. The Division issues licenses and registrations to all facilities that prescribe, dispense, distribute, or sell pharmaceuticals in the District. The Division also conducts inspections of community pharmacies, hospitals, penal institutions, substance abuse treatment programs, long-term care facilities, community residence facilities, drug wholesalers, drug manufacturers, drug researchers, dialysis programs, ambulatory centers, animal clinics, and stores that sell patent medicine products. The PCD also provides consultation services to all facilities and programs that supply pharmaceutical products and services to citizens in the District.

5. The PCD is understaffed and has difficulty fulfilling its assigned responsibilities.

The Chief of BFDRP stated that PCD has only four staff pharmacists to do the following:

- inspect 266 retail and community pharmacies for proper sanitation, hygienic standards, and proper storage of drugs; and
- investigate facilities and programs that provide pharmacy products and services.

Although all of the required 266 annual inspections were performed in 2000, PCD is often unable to complete other tasks, such as inspections and investigations of community drug and health services, because of its staffing shortage. The D/DOH was alerted to this problem in two Management Alert Reports, MAR 02-I-001 (Appendix 4), and MAR 02-I-005 (Appendix 2). DOH's response to MAR 02-I-001 was that "DOH . . . has committed to provide for a pharmacist to conduct work as it relates to hospitals, long term care facilities, day care facilities, renal dialysis centers, animal clinics and ambulatory care clinics" (Appendix 5). DOH's response to MAR 02-I-005 stated that "all drug-handling facilities in the last fiscal year were inspected as reported by the Program Manager." (Appendix 5). PCD now has 21 additional facilities that must be inspected.

The team believes that if all facilities that provide pharmaceutical products and services are not inspected and monitored for health and safety compliance on a timely basis, District citizens may be at risk of receiving medication or supplies that have expired or are otherwise defective.

Recommendation:

That D/DOH and the Chief of BFDRP ensure that a sufficient number of pharmacists are hired to carry out all of PCD's assigned responsibilities.

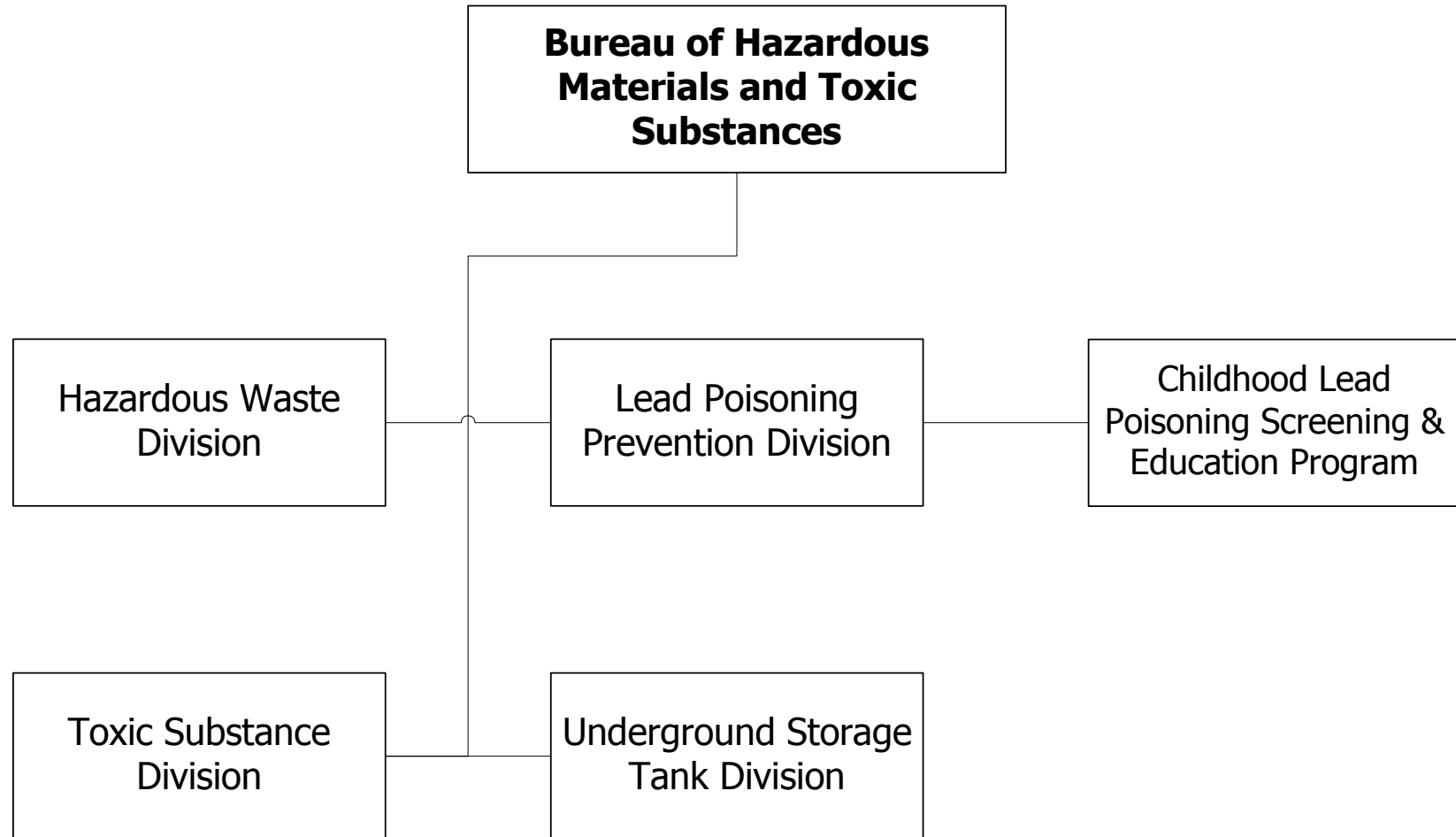
Agree _____ Disagree X

DOH's Response to IG's Recommendation, as Received:

The Bureau currently has sufficient staff to carry out all of its assigned responsibilities. To date, PCD is on target with scheduled inspections of all drug handling facilities.



Environmental Health Administration



Findings and Recommendations:

BUREAU OF HAZARDOUS MATERIALS AND TOXIC SUBSTANCES

BUREAU OF HAZARDOUS MATERIALS AND TOXIC SUBSTANCES

The Bureau of Hazardous Materials and Toxic Substances (BHMTS) was established in 1998 and is comprised of the Hazardous Waste Division, Underground Storage Tank Division, Toxic Substance Division, and Lead Poisoning Prevention Division. BHMTS has approximately 300 employees. Several District laws and regulations, including the Hazardous Waste Management Act of 1977, Title 20 of the District of Columbia Municipal Regulations (DCMR), and the federal Resource Conservation and Recovery Act (RCRA) regulate management of hazardous waste.

6. Delays and inaccuracies in drawing down federal grant funds adversely affect BHMTS programs.

Delays and errors by the DOH Chief Financial Officer (CFO) and the Grants Management Office (GMO) in drawing down grants adversely affect BHMTS programs, including the hiring of employees and the purchasing of equipment. The team found 11 federal grants that had to be returned unused because funds were not drawn down promptly, made available to BHMTS, and spent in a timely manner. BHMTS managers stated that there is also a problem drawing down correct grant amounts.

EHA does not have a liaison to work with the CFO and GMO to improve grant processing and decrease draw down delays.

Recommendation:

That D/DOH take steps to ensure that grant funds assigned to BHMTS are drawn down promptly and accurately, and that no funds are lost because of delays and errors.

Agree **X** Disagree _____

DOH's Response to IG's Recommendation, as Received:

The BHMTS agrees that grant funds should be drawn down promptly and accurately. Once a grant award letter has been received from the grantor, the program submits the letter to the DOH CFO. Once the award letter is submitted to the DOH CFO, the program has little control over the timeliness of the actual grant loading. Additionally, once a certificate of service has been provided by the program to the DOH CFO, the program has little control over the timeliness of the actual completion of draw downs. In particular, the administrative office overseeing the BHMTS, the Office of the Senior Deputy Director for Environmental Health Science and Regulation, does have staff that work as a liaison with the CFO to improve the grant process. The DOH CFO should be able to provide a more thorough response to this recommendation.

Hazardous Waste Division

The Hazardous Waste Division (HWD) has five employees including the Division Chief. HWD registers and inspects facilities that generate hazardous waste. It also regulates the generation, transportation, storage, treatment, and disposal of hazardous waste, and oversees remediation³ projects at active military facilities and former defense sites in the District. In addition, HWD conducts compliance inspections to ensure the proper treatment and disposal of hazardous waste.

There are approximately 637 facilities that generate hazardous waste in the District. These include 13 large-quantity generators at federal facilities. Other generators of hazardous waste include service-oriented businesses such as dry cleaners and auto-repair and printing shops, as well as hospitals, universities, and laboratories. In 2001, 243 tons of hazardous waste were generated in the District.

7. **HWD has only two inspectors to conduct 124 annual inspections and perform other assigned duties.**

HWD has two inspectors to conduct 124 annual inspections of all hazardous waste generators in the city. In addition, they must:

- respond to citizen complaints;
- conduct follow-up inspections;
- conduct emergency inspections (e.g., to investigate illegal dumping of hazardous waste);
- evaluate applications for the license renewal of hazardous waste generators; and
- attend community outreach meetings and litigation hearings.

Inspectors stated that because of the small staff, hazardous waste generators are not inspected annually, and follow-up inspections and license renewals are delayed. Inspectors stated that some federal facilities have not been inspected in over 10 years.

BHMTS management stated that there are not enough funds available to hire additional hazardous waste inspectors to carry out all of the division's duties.

³ "Remediation" is here defined as *the cleaning and removal of toxic substances from land*.

BUREAU OF HAZARDOUS MATERIALS AND TOXIC SUBSTANCES

Recommendation:

That D/DOH provide funding to hire additional HWD inspectors to ensure that all annual inspections and the remainder of HWD's responsibilities are conducted in a timely manner.

Agree _____ **X** _____ Disagree _____

DOH's Response to IG's Recommendation, as Received:

The HWD does agree that additional inspectors are required. However, the Division does not have additional grant funding to increase the number of inspectors, nor has the DOH CFO appropriated money for this purpose. The DOH CFO should be able to provide a more thorough response to this recommendation.

8. HWD inspectors do not have enough vehicles to conduct daily inspections.

HWD inspectors stated that there is only one official vehicle available to conduct inspections and that three vehicles are needed. BHMTS management stated that funds are available to purchase new vehicles; however, due to the delay in drawing down grant funds, additional vehicles cannot be purchased.

Recommendation:

That D/DOH purchase additional vehicles for the use of HWD inspectors.

Agree _____ **X** _____ Disagree _____

DOH's Response to IG's Recommendation, as Received:

The HWD does agree that additional vehicles are required. However, the Division does not have additional grant funding to increase the number of vehicles, nor has the DOH CFO appropriated money for this purpose. The DOH CFO should be able to provide a more thorough response to this recommendation.

Underground Storage Tank Division

The Underground Storage Tank Division (USTD) was established in 1985 and currently has 12 employees. These employees are responsible for conducting 150 underground storage tank inspections that are mandated by the District and the U.S. Environmental Protection Agency through a cooperative agreement work plan. Facilities are inspected whenever a UST is removed, abandoned, upgraded, repaired, or installed. Compliance inspections are conducted every three years for each facility.

USTD is also conducting:

- an investigation of the extent of contamination on the D.C. side of Eastern Avenue as a result of a release from a gas station located on the Maryland side;
- compliance inspections of all gas stations;
- a remediation oversight of the Alcohol, Tobacco, and Firearms site located at 145 O Street, N.E.; and
- remediation oversight of over 390 sites within the city.

9. The USTD surpassed the Mayor's FY 2001 scorecard goal of conducting 100 inspections.

The team found that the USTD had conducted 225 inspections for FY 2001, and received an award for outstanding achievement for excellence from the U.S. EPA.

Recommendation: None.

APPENDICES

APPENDICES

Appendix 1:	List of Findings and Recommendations
Appendix 2:	MAR 02-I-005
Appendix 3:	Response to MAR 02-I-005
Appendix 4:	MAR 02-I-001
Appendix 5:	Response to MAR 02-I-001

APPENDIX 1

LIST OF FINDINGS AND RECOMMENDATIONS

BUREAU OF FOOD, DRUG, AND RADIATION PROTECTION

1. **BFDRP inspectors do not have enough vehicles needed to conduct daily inspections.**

Recommendation:

That D/DOH and the Chief of BFDRP ensure that BFDRP employees have the vehicles necessary to conduct all inspections in a timely and effective manner in accordance with federal and District laws.

Radiation Protection Division

2. **The RPD is not inspecting x-ray machines in compliance with District law and its own inspection policy.**

Recommendations:

- a. That D/DOH ensure the proper calibration of devices used to inspect x-ray machines.
- b. That D/DOH act quickly to hire qualified contract or permanent employees to inspect all x-ray machines at regular intervals according to District law and DOH regulations.
- c. That D/DOH ensure that 20 DCMR § 2103.10 and the standard operating procedures of the RPD are clarified and updated to reflect clear time limits for the inspection of all District x-ray machines.

Food Protection Division

3. **FPD lacks ready access to updated listings of District food establishments needed to perform inspections.**

Recommendations:

- a. That D/DOH and the Chief of BFDRP coordinate with DCRA to ensure that a computer listing of all restaurants to be inspected is generated and maintained at FPD.
- b. That the Chief of BFDRP ensure that a computer database is developed that can retrieve the restaurant listings directly from DCRA's database.

LIST OF FINDINGS AND RECOMMENDATIONS

4. **Many FPD employees say they have not received the training required to maintain the skills, licenses, and certifications necessary to conduct inspections.**

Recommendation:

That D/DOH and the Chief of FPD allow FPD inspectors to attend continuing-education training to obtain and enhance skills, licenses, and certification.

Pharmaceutical Control Division

5. **The PCD is understaffed and has difficulty fulfilling its assigned responsibilities.**

Recommendation:

That D/DOH and the Chief of BFDRP ensure that a sufficient number of pharmacists are hired to carry out all of PCD's assigned responsibilities.

BUREAU OF HAZARDOUS MATERIALS AND TOXIC SUBSTANCES

6. **Delays and inaccuracies in drawing down federal grant funds adversely affect BHMTS programs.**

Recommendation:

That D/DOH take steps to ensure that grant funds assigned to BHMTS are drawn down promptly and accurately, and that no funds are lost because of delays and errors.

Hazardous Waste Division

7. **HWD has only two inspectors to conduct 124 annual inspections and perform other assigned duties.**

Recommendation:

That D/DOH provide funding to hire additional HWD inspectors to ensure that all annual inspections and the remainder of HWD's responsibilities are conducted in a timely manner.

8. **HWD inspectors do not have enough vehicles to conduct daily inspections.**

Recommendation:

That D/DOH purchase additional vehicles for the use of HWD inspectors.

LIST OF FINDINGS AND RECOMMENDATIONS

Underground Storage Tank Division

9. The USTD surpassed the Mayor's FY 2001 scorecard goal of conducting 100 inspections.

Recommendation: None.

APPENDIX 2

8

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General



April 26, 2002

Dr. Ivan C. A. Walks
Director
Department of Health
825 North Capitol Street, N.E.
Suite 4400
Washington, D.C. 20002

Re: Management Alert Report 002-I-001 Dated Dec 27, 2001, and DOH Response
Dated January 15, 2002.

Dear Dr. Walks:

This is a Management Alert Report ~~(MAR-02-I-005)~~ to inform you of important issues that have come to our attention during our ongoing inspection of the Department of Health (DOH). The Office of the Inspector General (OIG) provides these reports when we believe a serious matter requires the immediate attention of a District of Columbia government official.

OIG Inspectors continue to receive complaints that Bureau of Food, Drug, and Radiation Protection (Bureau) management is not devoting adequate attention to the following inspection problems affecting the health and safety of District citizens:

- (a) The number of Bureau employees who inspect drug handling facilities and hazardous waste generators is insufficient, and critical inspections of these entities are not being conducted;
- (b) There is an insufficient number of vehicles available for inspectors to conduct Bureau inspections efficiently and in a timely manner; and
- (c) Many Bureau employees are not receiving the training required to maintain the skills, licenses, and certifications required to conduct inspections effectively.

These deficiencies were brought to the attention of DOH senior management in December 2001. They may pose an immediate danger to public health; may increase the risk of fraud, waste, and abuse among those who handle drugs and hazardous wastes; and may have negative fiscal implications for the District government. Information provided to this Office indicates that appropriated funds or grants that would help alleviate some of these problems have been made available to Bureau management, but management has not made use of these funds.

a. Insufficient Staffing and Inspections

Pharmaceutical Control Division. The Pharmaceutical Control Division (PCD) has come to a virtual standstill on conducting inspections because it lacks adequate staff. In the December 2001 MAR (Attachment 1), the OIG informed the Director of DOH that PCD was not inspecting all District sites that dispense or sell pharmaceuticals because it did not have enough pharmacists. At that time, PCD had only three pharmacists and was unable to carry out its full load of inspections as well as handle its other responsibilities that include conducting medical fraud investigations. In response to our MAR recommendation that DOH "take immediate steps" to hire additional pharmacists, DOH stated that it "has committed to provide for a pharmacist" (Attachment 2).

We have learned, however, that PCD now has no pharmacists other than the PCD supervisor, and she must handle all tasks assigned to PCD. There are more than 280 sites and programs where PCD pharmacists must check medication expiration dates and the proper dispensing of medication, review pharmacy records, and assess the cleanliness and other aspects of pharmaceutical operations. The PCD supervisor has worked additional, uncompensated hours in an effort to manage this workload, and has no clerical or administrative support. This staffing deficiency endangers recipients of prescription drugs and controlled substances, and increases the risk of fraud, waste, and abuse at uninspected locations.

In addition to her routine duties, the current PCD supervisor is the District's Chief Pharmacist during crisis situations such as the anthrax attacks, and is responsible for the distribution of pharmaceuticals shipped into the city before or during such crises. Consequently, she has many liaison responsibilities with agencies such as the Drug Enforcement Administration, the Federal Bureau of Investigation, and the Metropolitan Police Department. This additional workload and the lack of any support staff make it virtually impossible for PCD to effectively safeguard the public from pharmaceutical hazards, fraud, and abuse by means of its routine inspections. The PCD supervisor stated that she *needs at least three full-time pharmacists* in addition to herself in order to conduct required inspections.

Radiological and Medical Services Division. The Radiological and Medical Services Division (RHMD) continues to have a serious backlog of inspections and tests of all of the District's approximately 750 x-ray machines and its 29 mammography machines located in hospitals, outpatient clinics, dental offices, veterinary clinics and other facilities. Uninspected x-ray equipment may be improperly maintained or malfunctioning, and could expose District citizens to dangerous amounts of harmful radiation. In the December 2001 MAR, we alerted DOH to this backlog (some harmful x-ray machines had not been inspected and calibrated in years), and the insufficient number of health physicists employed to conduct the required inspections. We recommended that additional employees be hired quickly so that DOH would be in compliance with the requirements for these inspections. However, RHMD still has only two full-time inspectors for this task and no clerical or administrative support. Based on staffing ratios

recommended by the Conference of Radiation Control Program Directors, Inc.,¹ RHMD should have a minimum of five inspectors for the city's x-ray machines and one inspector for mammography machines. The referenced DOH response to our MAR stated that a "highly qualified health physicist" had been hired. We have learned, however, that the newly hired health physicist was quickly promoted into a supervisory position, and consequently, has provided only limited help in reducing the backlog of routine inspections. In addition, RHMD does not appear to have specific goals or timetables for reducing its inspection backlog. Bureau management stated that the Division needs *a minimum of four additional health physicists*.

b. Vehicle Availability

The Bureau has only 2 government vehicles for 23 inspectors who must work in every section of the city. Although inspectors make maximum use of public transportation, its effectiveness is limited because of the widely dispersed locations of the inspection sites. In addition, the use of public transportation can be inordinately time-consuming and restricts the number of inspections that can be completed each month. Bureau employees report that they frequently use their own vehicles, without reimbursement, in order to conduct their inspections as expeditiously as possible so that the District is in compliance with applicable laws.

c. Lack of Training Opportunities

Inspectors throughout the Bureau complain that management refuses to allow them to attend the training required by their professions. Pharmacists, for example, must have 15 hours of training each year in order to renew their licenses. Food and hazardous waste inspectors have similar training needs in order to maintain their certifications and skills, and to keep them up-to-date with technological advancements and changes in their respective fields. Some inspectors stated that they have used personal funds to pay for required training. Insufficiently trained or uncertified/unlicensed inspectors working in food, drug, and radiation protection obviously put District citizens and the District government at an increased risk of harm and fiscal loss.

Recommendations:

That you act quickly to ensure that the Bureau of Food, Drug, and Radiation Protection has the staff and vehicles necessary to eliminate its inspection backlog, and to conduct all inspections in a timely and effective manner in accordance with federal and District laws.

That you ensure that Bureau inspectors are given the opportunity and means to attend all training required by their professions for renewal of certifications and licenses, and maintenance of their knowledge and skills.

¹ The Conference of Radiation Control Program Directors, Inc. is a national organization whose primary members are radiation professionals in state and local government who regulate the use of radiation sources. The current Director of the DOH Bureau of Food, Drug, and Radiation Protection is a member.

Letter to Ivan C. A. Walks

April 26, 2002

Page 4

That you determine the extent to which Bureau management should be held accountable for the problems described in this MAR, and take quick and appropriate action to correct any managerial deficiencies.

Please provide your comments on this report by May 10, 2002. Your response should include actions taken or planned, dates for completion of planned actions, and reasons for any disagreement with the concerns and recommendations presented. Please distribute this Management Alert Report to only those personnel who will be directly involved in preparing your response.

Should you have questions or desire a conference prior to preparing your response, please contact Director of Planning and Inspections Melvina Coakley, 202-727-8490.

Sincerely,

A handwritten signature in blue ink, appearing to read "Charles C. Maddox".

Charles C. Maddox, Esq.
Inspector General

Enclosures (2)

CCM/MLC/jcs

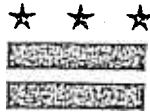
cc Mr. John A. Koskinen, Deputy Mayor and City Administrator, Office of the City Administrator
Ms. Carolyn N. Graham, Deputy Mayor, Children, Youth and Families

APPENDIX 3

GOVERNMENT OF THE DISTRICT OF COLUMBIA

Department of Health

Office of the Director



5/31/02
[#368]

May 31, 2002

Charles C. Maddox, Esq.
Inspector General
Office of the Inspector General
717 14th Street N.W.
Suite 500
Washington, D.C. 20005

Dear Mr. Maddox:

Please find the Department of Health (DOH) response to your Management Alert Report (MAR 02-I-005) letter dated April 26, 2002.

Specifically, you stated that you "continue to receive complaints that the Bureau of Food, Drug, and Radiation Protection (Bureau) management is not devoting adequate attention to inspection problems affecting the health and safety of District citizens."

DOH would like to respond point by point to those complaints.

Complaint:

- (a) The number of Bureau employees who inspect drug handling facilities and hazardous waste generators is insufficient, and critical inspections of these entities are not being conducted;

DOH Response:

All drug-handling facilities in the last fiscal year were inspected as reported by the Program Manager. This fiscal year the Pharmaceutical Control Division (PCD) added 21 facilities, which in the past had been inspected by other professionals as part of their inspection (i.e. animal clinic inspected by the veterinarian). PCD currently has three registered pharmacists available to conduct inspections and the selection of a fourth pharmacist has been made and is expected on board by May 31, 2002.

The Bureau of Food, Drug and Radiation Protection (BFDRP) does not inspect hazardous waste generators nor does it have any mandate to inspect these facilities. This function is under the Bureau of Hazardous Material and Toxic Substances.

Complaint:

- (b) There is an insufficient number of vehicles available for inspectors to conduct Bureau inspections efficiently and in a timely manner;

DOH Response:

- It is true that the Bureau has only two cars but 90% of the staff when polled indicated the desire to use their own private vehicles. The BFDRP has identified funding for the purchase of 5 new automobiles (compressed natural gas) in FY03. Even with this vehicle shortage, the BFDRP has never failed to meet its projected program measures.

Complaint:

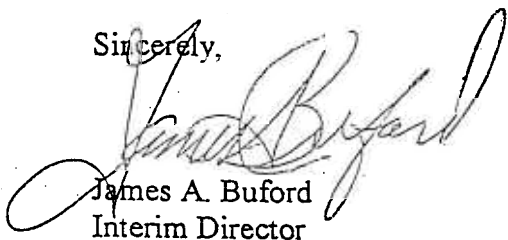
- (c) Many Bureau employees are not receiving the training required to maintain the skills, licenses, and certifications required to conduct inspections.

DOH Response:

Only one employee is required by a contract with the Federal Government to receive specialized training (Mammography), and that individual, the health physicist has received training that will last for three years. The certification will not have to be renewed until 2005. The bureau encourages employees to take courses to increase their knowledge as exemplified by Ms. Jacqueline Coleman who has taken or attended 25 courses/classes (see certificates/letters) since 1999. Annually, the bureau has invested over 2000 man-hours for training and classes for staff.

We hope that we have clarified the issues stated above. If you have any other questions, please do not hesitate to contact me.

Sincerely,



James A. Buford
Interim Director

Enclosures

Cc: John A. Koskinen, City Administrator, Office of the City Administrator
Carolyn Graham, Deputy Mayor for Children, Youth, and Elders

APPENDIX 4

1
LOR

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General



December 27, 2001

Dr. Ivan C. A. Walks
Director
Department of Health
825 North Capitol Street, Northeast
Suite 4400
Washington, DC 20002

Dear Dr. Walks:

This is a Management Alert Report (MAR 02-I-001) to inform you of two important issues that have come to our attention during our inspection of the Environmental Health Administration. The Office of the Inspector General (OIG) provides these reports when we believe a serious matter requires the immediate attention of a District of Columbia government official.

1. The Radiological Health and Medical Devices Division is not inspecting x-ray machines in compliance with District law and its own inspection policy.

Background

Title 20 DCMR §2103.10 states that: [e]ach radiation device (x-ray machine) used in the District shall be re-tested at not longer than six (6) month intervals, or at intervals not to exceed three (3) years as is specified in the label required by this section.

(Attachment 1).

While this language is somewhat confusing, the chief of the Radiological Health and Medical Devices Division (RHMD) stated that his division's policy is to inspect all x-ray machines every 2 years. However, RHMD's Standard Operating Procedures do not identify an inspection interval for x-ray machines (Attachment 2). In addition, the inspection team also determined that some x-ray machines being used in the District have not been inspected in as many as 10 years.

There are 1500 x-ray machines being used in various facilities in the city that require inspection. They are located in hospitals, clinics, dental offices, veterinary clinics, Metropolitan Police and correctional institutions, and other locations. According to the division chief, only a small percentage of these machines are currently being inspected because he has only one employee—

a health physicist—who is qualified to conduct the required inspections. The division chief stated that he needs two to four qualified inspectors in order to comply with District law.

The inspection team requested a list of the most recent inspections of the city's 1500 x-ray machines. Instead of a list, the RHMD Division Chief provided inspection reports that appear to show that only 43 inspections were conducted between January 2000 and October 2001. In addition, the reports contain few details about the items inspected, and do not show if items listed in RHMD's Standard Operating Procedures to be evaluated were in fact evaluated (Attachment 3). However, the health physicist stated that inspections of x-ray machines are counted according to how many fluoroscopic and radiographic tubes are installed in a machine. The inspection of an x-ray machine equipped with two tubes is counted as two inspections. Consequently, the health physicist stated that rather than the 43 inspections the reports appear to show, approximately 600 inspections have been conducted for that same period of time.

The chief of the Radiation Health and Medical Devices Division and the chief of the Environmental Health Administration are directly responsible for ensuring that x-ray machines being used in the District are properly licensed and are inspected at appropriate intervals. The chief RHMD and the chief EHA are also directly responsible for ensuring that x-ray machines being used in the District are properly calibrated to ensure the safety of District citizens. The inspection team determined that some of the equipment RHMD uses to inspect x-ray machines has not been calibrated for approximately 3 years, and believes that all those who operate and who are examined by un-inspected x-ray machines, or by x-ray machines that have been inspected by uncalibrated or faulty equipment, are at risk of over-exposure to hazardous radiation.

Recommendations:

That DOH take immediate steps to ensure the proper calibration of machines used to inspect x-ray machines.

That DOH consider taking immediate steps to hire qualified contract or permanent employees to inspect all x-ray machines in the District that have not been inspected according to District law and DOH regulations.

That DOH oversee coordination between the appropriate District and DOH officials to ensure that Title 20 DCMR §2103.10 and the Standard Operating Procedures of the Radiological Health and Medical Devices Division are clarified and updated to reflect clear time limits for the inspection of all District x-ray machines.

2. The Pharmaceutical Control Division is not inspecting all District sites that dispense or sell pharmaceuticals.

The Pharmaceutical Control Division (PCD) does not have enough pharmacists to inspect all of the more than 280 pharmaceutical sites and programs in the District to ensure they are in compliance with 20 DCMR §1925.2 (Attachment 4). PCD is required to check medication expiration dates and the proper dispensing of medication, review pharmacy records, and assess

the cleanliness of facilities, as well as other aspects of pharmaceutical operations. Although the PCD staff stated that the annual goal of inspecting all 129 pharmacies in the city is being met, inspections of other facilities such as hospitals without pharmacies, substance abuse treatment programs, research facilities, long-term care facilities, and retail stores are not being conducted (Attachment 5). A staff pharmacist stated that these inspections are not being carried out because of the staff's additional job duties, such as conducting investigations of medical fraud, and inspections of hospitals, research facilities, local wholesalers/distributors, long term care and community facilities, animal and ambulatory clinics, and dialysis centers with controlled substances. There are also 35 programs under the new Certification of Substance Abuse Treatment and Facilities Program that dispense pharmaceuticals but cannot be evaluated because PCD lacks sufficient staff.

The inspection team believes that patients and other citizens of the District are at risk of receiving and ingesting expired, contaminated, and incorrect medication if facilities that dispense or sell pharmaceuticals are not inspected on a timely basis. In addition, the lack of such inspections eliminates a significant source of information that can lead to the detection of fraud, waste, and abuse.

Recommendations:

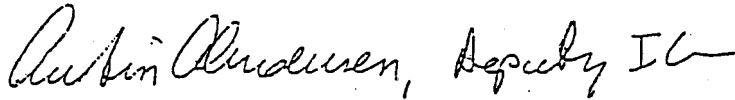
That DOH consider taking immediate steps to hire qualified contract or permanent pharmacists to inspect all pharmaceutical facilities and sites in the District that are not being inspected according to District law.

Please provide your comments on this report by January 10, 2002. Your response should include actions taken or planned, dates for completion of planned actions, and reasons for any disagreement with the concerns and recommendations presented. Please distribute this Management Alert Report only to those personnel who will be directly involved in preparing your response.

Should you have questions concerning this report or desire a conference prior to preparing your response, please contact Director of Planning and Inspections Melvina Coakley, 202-727-8490.

Letter to Ivan C. A. Walks
December 27, 2001
Page 4

Sincerely,

Handwritten signature of Charles C. Maddox, Esq.

per Charles C. Maddox, Esq.
Inspector General

Enclosure/Attachment

CCM/MLC/jcs

cc: Mr. John A. Koskinen, Deputy Mayor and City Administrator, Office of the City
Administrator
Ms. Carolyn N. Graham, Deputy Mayor, Children, Youth and Families

APPENDIX 5

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health

Office of the Director

★ ★ ★

JAN 15 2002

Charles C. Maddox, Esq.
Inspector General
717 14th Street, N.W., Suite 500
Washington, D.C. 20005

Ref: MAR 002-I-001

Dear Mr. Maddox:

The Department of Health submits the following responses to the above referenced Management Alert Report regarding issues with the Radiological Health and Medical Devices Division and the Pharmaceutical Control Division.

Radiological Health and Medical Devices Division

Recommendation:

- That DOH take immediate steps to ensure the proper calibration of machines used to inspect x-ray machines.

Response:

The Department of Health, Environmental Health Administration, Bureau of Food, Drug and Radiation has four (4) radiation monitors (MDH) of which two (2) are currently calibrated with expiration dates ending on November 2002 and December 2002.

Recommendation:

- That DOH consider taking immediate steps to hire qualified contractors or permanent employees to inspect all x-ray machines in the District that have not been inspected according to District law and DOH regulations.

Response:

The Bureau of Food, Drug, and Radiation has a highly qualified health physicist who reported for duty on Monday, January 14, 2002.

- 2 -

Recommendation:

- That DOH oversee coordination between the appropriate District and DOH officials to ensure that Title 20 DCMR S2103.10 and the Standard Operating Procedures of the Radiological Health Medical Devices Division are clarified and updated to reflect clear limits for the inspection of all District x-ray machines.

Response:

BFDRP has begun the process of updating the 30 year old radiation regulations with help of the Legal Law Institute and DOH's Office of Compliance, Enforcement and Environmental Justice.

- Pharmaceutical Control Division

Recommendation:

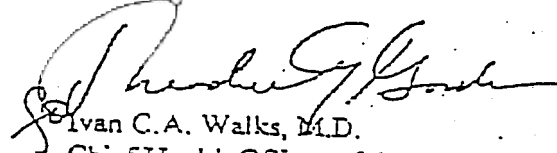
- That DOH consider taking immediate steps to hire qualified contract or permanent pharmacists to inspect all pharmaceutical facilities and sites in the District that are not being inspected according to District Law.

Response:

DOH's Health Regulation Administration has committed to provide for a pharmacist to conduct work as it relates to hospitals, long term care facilities, day care facilities, renal dialysis centers, animal clinics and ambulatory care clinics.

We thank you for the opportunity to respond to your recommendations. If you require any additional information or assistance, please feel free to contact me at (202) 442-5999.

Sincerely



Ivan C.A. Walks, M.D.
Chief Health Officer of the
District of Columbia
Director, Department of Health

Cc: Mr. John A. Koskinen, Deputy Mayor and City Administrator, Office of the City Administrator
Ms. Carolyn N. Graham, Deputy Mayor, Children, Youth and Families